

**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

PL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/123,614 07/28/98 MIDDLEMAN

L 12032

┌

QM12/0123

└

EXAMINER

DAVID A. FARAH, M.D.
SHELDON & MAK
225 SOUTH LAKE AVENUE 9TH FLOOR
PASADENA CA 91101

RODRIGUEZ, C

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

01/23/01

14

**Please find below and/or attached an Office communication concerning this application r
proceeding.**

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/123,614

Applicant(s)

Middleman et al

Examiner

CJR

Group Art Unit

3763

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/30/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2, 7-11, 22, 24-59 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 7-11, 22, 24-59 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 3763

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1, 2, 7-11, 22, 24-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 28, 38, and 48, the word "means" is preceded by the word(s) "deployment" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Art Unit: 3763

3. Claims 1, 2, 11, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cathcart et al(5,681,347).

Cathcart et al disclose a device 10 comprising a tubular element 13 comprising a hollow tubular lumen, a deployment means 17, and a plurality of resilient anchoring members 24 attached to the distal end of the inner lumen as claimed. Please note that the word “attached” means to join or connect. The word join is being used as “to put into close association or relationship” according to the Webster’s II dictionary.

4. Claims 1, 2, 7, 10, 11, 22, 48-50, 53-55 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goldberg et al(5,152,777).

Goldberg et al discloses a device comprising a tubular element 70,72,74 comprising a hollow tubular lumen, a deployment means 60,90,92(also considered as the guide wire set forth in claims 7, 40 and 50), and a plurality of resilient anchoring members 32A-32F as claimed. The collar is reference numeral 38.

5. Claims 38-40, 44 and 45 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hayashi(5,910,144).

Hayashi discloses a prothesis gripping system comprising a tubular element 20,26 comprising a hollow tubular lumen, a deployment means 50(the guide wire set forth in claims 7, 40 and 50 is reference numeral 36), and a plurality of resilient anchoring members 40 as claimed. The collar is reference numeral 50.

Art Unit: 3763

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over et al Cathcart et al in view of Hayman et al(5,267,960) and Abrams(5,492,119).

Cathcart et al disclose the invention substantially as claimed. However, Cathcart et al does not disclose the anchoring members comprising spring steel or a pseudo elastic material such as nickel titanium alloy.

Hayman et al teaches an anchor 19 having arms 21 made of spring steel, and Abrams teaches a catheter apparatus comprising control wires having curved feet made of nitinol which is a pseudo elastic material for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cathcart et al by providing the anchoring members with the materials as disclosed by Abrams and Hayman et al as old taught and well known in the art for anchoring purposes.

8. Claims 8, 9, 26, 51, 52, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. in view of Abrams.

Art Unit: 3763

Goldberg et al discloses the invention substantially as claimed as discussed supra. However, Goldberg et al does not disclose the anchoring members being of a pseudo elastic material such as nickel titanium alloy, or the anchoring members having an oval cross-section.

Abrams teaches a catheter apparatus comprising control wires having curved feet made of nitinol which is a pseudo elastic material for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg et al by providing the anchoring members with the materials as disclosed by Abrams as old taught and well known in the art for anchoring purposes. Also, the oval cross-section is an obvious variation from the circular cross-section.

9. Claims 27 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Lefebvre(5,938,683).

Goldberg et al discloses the invention substantially as claimed as discussed supra. However, Goldberg et al does not disclose the anchoring members having a substantially flat top portion.

Lefebvre teaches a filter(anchoring member) comprising a substantially flat top portion for anchoring purposes in a blood vessel(see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg et al by providing the anchoring members with the substantially flat top portion as shown by Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

Art Unit: 3763

10. Claims 24, 25, 28-30, 33-36, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Hayashi.

Goldberg et al discloses a device comprising a tubular element 70,72,74 comprising a hollow tubular lumen, a deployment means 60,90,92(also considered as the guide wire set forth in claims 7, 40 and 50), and a plurality of resilient anchoring members 32A-32F as claimed. The collar is reference numeral 38. However, Goldberg et al does not disclose the anchoring members being attached within the wall of the deployment means inner lumen, or attached to the inner surface of the wall of the deployment means inner lumen, and the anchoring members having a substantially oval cross-section.

Hayashi teaches a device with anchoring members 40 being attached to the inner surface of the wall of the deployment means 50 inner lumen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg et al by attaching the anchoring members to the inner surface of the wall of the deployment means 50 inner lumen as taught old and well known by Hayashi as an alternative design of connection between two segments. Since Applicant's disclosure lacks criticality for attaching the anchoring members within the wall of the deployment means, the Examiner has considered this feature as a mere modification or variation from the Goldberg et al(over the outer surface of the deployment means) and Hayashi(in the inside surface of the deployment means) connections. Also, the oval cross-section is an obvious variation from the circular cross-section.

Art Unit: 3763

11. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg in view of Hayashi as applied to claim 28 above, and further in view of Abrams.

Goldberg in view of Hayashi discloses the invention substantially as claimed as discussed supra. However, Goldberg et al in view of Hayashi does not disclose the anchoring members comprising a pseudo elastic material such as nickel titanium alloy.

Abrams teaches a catheter apparatus comprising control wires having curved feet made of nitinol which is a pseudo elastic material for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg et al in view of Hayashi by providing the anchoring members with the materials as disclosed by Abrams as old taught and well known in the art for anchoring purposes.

12. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Hayashi as applied to claim 28 above, and further in view of Lefebvre.

Goldberg in view of Hayashi discloses the invention substantially as claimed as discussed supra. However, Goldberg et al in view of Hayashi does not disclose the anchoring members having a substantially flat top portion.

Lefebvre teaches a filter(anchoring member) comprising a substantially flat top portion for anchoring purposes in a blood vessel(see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg et al in view of Hayashi by providing the anchoring members with the substantially flat top portion as shown by

Art Unit: 3763

Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

13. Claims 41- 43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Abrams and Hayman et al.

Hayashi discloses the invention substantially as claimed as discussed supra. However, Hayashi does not disclose the anchoring members being of a pseudo elastic material such as nickel titanium alloy or made of spring steel, or the anchoring members having a substantially oval cross-section.

Abrams teaches a catheter apparatus comprising control wires having curved feet made of nitinol which is a pseudo elastic material, and Hayman et al teaches an anchor 19 having arms 21 made of spring steel for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hayashi by providing the anchoring members with the materials as disclosed by Abrams and Hayman et al as old taught and well known in the art for anchoring purposes. Also, the oval cross-section is an obvious variation from the circular-cross section.

14. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Lefebvre.

Hayashi discloses the invention substantially as claimed as discussed supra. However, Hayashi does not disclose does not disclose the anchoring members having a substantially flat top portion.

Art Unit: 3763

Lefebvre teaches a filter(anchoring member) comprising a substantially flat top portion for anchoring purposes in a blood vessel(see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hayashi by providing the anchoring members with the substantially flat top portion as shown by Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

Response to Arguments

15. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant is being narrower than the claims. In regards to Applicants arguments that Cathcart et al does not have the bore of the inner lumen extending completely through the inner lumen from the proximal to the distal end. This is not found persuasive because in column 6 lines 26-38 of the reference set forth that the tube is hollow from proximal to distal end. The description in claim 1 of reversibly movable is limited or incomplete because it only provides the description from a first and a second position which the reference can perform.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nady-Mohamed, Javier Jr.et al, Chevillon et al, Lindenberg et al, Mobley et al, Bates, Gaber, Kirkman, Broome et al, and Tsugita et al all disclose devices analogous to that as claimed.


Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, Richard Seidel can be reached on (703) 308-5115. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

CLR 1/10/01
Cris L. Rodriguez
January 10, 2001


RICHARD K. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700